

Appl. No. : 10/776,309  
Filed : February 11, 2004

### **REMARKS**

Claims 31, 32, 34-49, 99-102, and 124-127 remain pending in the present Application, Claims 31, 99 and 100 having been amended. The claims set forth above include markings to show the changes made by way of the present amendment, deletions being in ~~strikeout~~ or ~~[[double brackets]]~~ and additions being underlined.

In response to the Office Action mailed December 30, 2010, Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

#### **Claims 49, 126, and 127 are Allowed**

Applicants gratefully acknowledge the Examiner's indication that Claims 49, 126, and 127 remain allowed.

#### **The Claim Present Amendments are Fully Supported by the Specification**

By way of the present Amendment, Claims 31 and 99 have been amended to include subject matter that is fully supported by the specification as originally filed. Thus, Applicant submits that no new matter has been entered.

With regarding to the amendments to Claims 31 and 99 with regard to the relaxed state of the aperture or elastically enlargeable aperture, Applicant respectfully directs the Examiner to paragraphs [0220]-[0226] of the present Specification, which describes the size of the aperture 73, the size of the rim 98 of the flexible shield 95 (with reference to Figures 12 and 13), as well as the process for fitting the aperture 73 over the rim 98.

Thus, Applicant submits that all of the amendments are fully supported by the present specification as originally filed.

#### **The Proposed Combination of Johnson/Smith/Greco Does Not Make Amended Claims 31, 34-48, and 124 Obvious**

Claims 31, 34-48, and 124 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,311,838 issued to Johnson *et al.* ("Johnson") in view of U.S. Patent No. 6,402,724 issued to Smith *et al.* ("Smith") and further in view of U.S. Patent No. 5,312,385 issued to Greco ("Greco"). Applicant respectfully traverses the present rejection. However, in order to expedite the prosecution of the present application, Applicant has amended independent

Claim 31. Applicant also expressly reserves the right to further prosecute the original versions of Claim 31 and any claims dependent on it through continuation practice.

Johnson discloses, as described in the Amendment filed October 29, 2010, an integrated packaging system for packaging medical components. The packaging system includes a lid 20 which can be flipped over to convert the packaging system from a shipping mode to a disposal mode, wherein the lid is removable in the shipping mode and non-removable in the disposal mode. *See Johnson at 7:66-8:37.* Angled grooves provide the removable/non-removable functionality. *Id.*

The Office Action asserts: “The different between Johnson and claim 31 is the provision that the kit specifically includes a flexible sheet.” Office Action at p. 2. The Office Action further asserts that Smith teaches “a wound irrigation shield that includes a flexible sheet with an adjustable aperture as set forth in the abstract.” *Id.*

Smith teaches a splash shield for use in wound irrigation. The splash shield is made of flexible material “to adapt to the fluid end portion of any number and variety of irrigation fluid delivery devices.” Smith, Abstract. See also Figures 1 and 2 from Smith reproduced below.

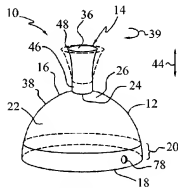


FIG. 1

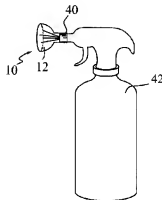


FIG. 2

Applicant notes that the splash shield of Smith, illustrated above, is in fact, a *conical splash shield* having a narrowed collar portion and an enlarged distal rim. Applicant would like to note that this conical splash shield appears to be *essentially the same* as the conical splash shield illustrated in **Figure 13 of the present Application**. However, no combination of Smith and Johnson would result in a device having the *conical splash shield* of Smith, *plus an additional*

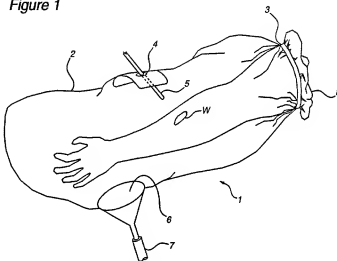
*transparent flexible sheet* having an aperture designed to fit over the conical splash shield of Smith. In other words, the combination of Johnson and Smith would only result in a medical kit having an irrigation device and the conical splash shield of Smith. Nothing in the teachings of Smith and Johnson would teach or suggest that such a kit should *further include a flexible transparent sheet* that includes an aperture designed specifically to fit over and around the enlarged distal rim of the Smith splash shield so that it can fit against the narrowed collar (46) of the Smith splash shield.

Applicant recognizes that the Office Action goes on to indicate that the Greco reference, Figure 1 of which is reproduced adjacent hereto, teaches using a plastic bag to collect irrigation fluid during a wound irrigation procedure. More specifically, Greco teaches a plastic bag having a port 4 for receiving a tubular irrigation nozzle 5.

However, this irrigation nozzle 5 does not include a *conical structure* having a narrowed throat portion extending to an enlarged distal portion. Additionally, the plastic bag of Greco is secured to the patient. Thus, the fully assembled combination taught by Greco is not a device that allows the surgeon substantial freedom in moving the irrigation nozzle 5 relative to the wound W. Rather, the movement of the nozzle 5 is quite restricted due to the structural arrangement of the components illustrating Greco.

In contrast, Claim 31 now recites, among other recitations, “wherein the aperture, in an enlarged state, is configured to fit over a conical splash shield extending distally from a collar attached to a tip of the irrigation device, the conical splash shield having a conical shape extending from a smaller diameter portion at the collar to a larger diameter at an open distal end, wherein the aperture when in a relaxed state is smaller than the open end and thereby remains connected to the irrigation device; wherein the flexible sheet is sized to cover a wound area and the basin”.

Figure 1



This distinction is important because, as disclosed in the present Application, by providing the flexible sheet with an *enlargeable aperture* that fits over a standard splash shield of an irrigation nozzle, a practitioner can rapidly and conveniently attach this flexible sheet to a standard irrigation nozzle and yet retain freedom to move the handheld irrigation nozzle around the wound of the patient. As such, the flexible sheet does not have to be sized or appropriated adapted for any particular anatomy.

Rather, the flexible sheet can simply be held up by the practitioner and/or an additional assistants, and allow for rapid and large volume irrigations of wounds. There is no need to provide for a specific placement of a port, such as that illustrated in Greco, which would necessarily inhibit and/or limit the movement of an irrigation nozzle around a wound.

Thus, Applicant submits that no obvious combination of the Johnson, Smith and Greco references could possible result in a kit having an irrigation device with a conical splash shield having a narrowed collar portion and an enlarged distal open rim, as well as a flexible sheet having an aperture specifically designed to stretch over the enlarged distal rim of that splash shield so that it can be secured to the collar portion of the irrigation device. As noted above, this provides a fast and convenient way to attach this flexible sheet to the irrigation device, which provides substantial freedom for the practitioner during an operation. The present Specification, as originally filed, explains these advantages as follows:

[0220] With reference to Figure 12, an irrigation shield 70 is illustrated therein. The irrigation shield 70 comprises a sheet 71 and an aperture 73 disposed at a central portion of the sheet 71. **The aperture 73 is configured to be stretched from a resting state to an enlarged state.** The sheet 71 is flexible and thus can be shaped to define an open end 74.

[0221] An elastic member 73b preferably attaches circumferentially to the sheet 71, around the aperture 73 and is **configured to be modified from a resting state to an enlarged state for use with an irrigation device such as the one disclosed in U.S. Patent Number 6,156,004, discussed below.** The member 73b is further configured to generate a gripping force. In the illustrated embodiment, the elastic member 73b is an elastic band. The elastic member 73b can optionally be a latex portion attached circumferentially around the aperture 73, the latex portion having an elastically enlargeable opening configured to receive the irrigation device. The member 73b is preferably attached to the sheet 71 with glue. However, the member 73b can be attached to the sheet 71 in a number of ways, such as, but without limitation, by being sewn to the sheet 71.

[0225] When the tip 82 is connected to the handpiece 81 and the handpiece 81 is energized, irrigation fluid passes through the irrigation port 90 and into the tip 82. The irrigation fluid is emitted from a distal end 92 of the tip 82 at a frequency controlled by the handpiece trigger 93. The tip 82 includes a flexible splash shield 95 and connector 96. The connector 96 is disposed at a proximal end 94 of the tip 82 and detachably connects the tip 82 to the handpiece 81. The flexible shield 95 includes a proximal collar 97 and a conical body that diverges in a distal direction to a distal rim 98. The collar 97 is slidably mounted to an irrigation tube 99 comprised by the tip 82. **Vent holes 100 disposed on the shield 95 are configured to prevent the shield from collapsing when the irrigation device 80 is operated in a suction mode.** A stop ridge 102 may circumscribe the proximal end of the irrigation tube 99 to prevent the splash shield 95 from being retracted into contact with the connector 96.

[0226] During operation, medical personnel connect the handpiece 81 to the tip 82 and fit the rim 98 of the shield 95 through the aperture 73 in its enlarged state so that the elastic member 73b preferably rests around the collar 97. The elastic member 73b preferably generates a gripping force on the collar to substantially prevent the elastic member 73b from sliding along the collar 97. Personnel optionally shorten the length 76 of the sheet 71 as desired. For example, personnel can cut the sheet 71 a desired distance circumferentially around the axis 72. Medical personnel preferably cut the sheet 71 with scissors, but may optionally use any sharp object.

[0227] Medical personnel then place the open end 74 of the sheet 71 so that it is disposed over the wound region of the patient. **For example, if the wound is on the knee-area, as discussed above, personnel can place the sheet 71 over the injured leg of the patient so that it covers the wound area and the basin 10. Personnel then actuate the irrigation device by pressing the trigger 93 to emit irrigation fluid from the tip 82. Irrigation fluid is then directed to the wound area of the patient, which is then collected in the basin.**

Present Specification, paragraphs [0220], [0221], and [0225-[0227]] (emphasis added).

Applicant's also acknowledge the Examiner's indication that the conical splash shield is not positively recited and thus is not part of the claim. However, Applicant's note that the recitations of Claim 31 (and 99) directed to the size and configuration of the aperture on the sheet are positively recited. Additionally, some of these recitations may be considered to be in a functional form, yet should be afforded patentable weight as structural limitations.

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More specifically, Applicant would like to point out that it has long been established that structural claim limitations may be in the form of functional recitations. For example, MPEP § 2173.05(g) states:

A functional limitation is an attempt to define something by what it does, rather than by what it is (e.g., as evidenced by its specific structure or specific ingredients). **There is nothing inherently wrong with defining some part of an invention in functional terms.** Functional language does not, in and of itself render a claim improper.

A functional limitation **must be evaluated and considered**, just like any other limitation of the claim, for what it *fairly conveys to a person of ordinary skill* in the pertinent art in the context in which it is used.

In a claim that was directed to a kit of component parts capable of being assembled, the Court held that limitations such as “members **adapted to be positioned**” and “portions . . . being **resiliently dilatable whereby said housing may be slidably positioned**” serve to precisely define present structural attributes of interrelated component parts of the claimed assembly. In re Venezia, 530 F.2d 956, 189 USPQ 149 (CCPA 1976).

MPEP § 2173.05(g) (emphasis added).

Thus, Applicant respectfully requests that the Examiner apply, to the recitations set forth in Claims 31 and 99 directed to the aperture in the flexible sheet, the meanings that would be *fairly conveyed to* one of ordinary skill in the art.

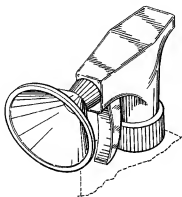
Accordingly, Applicant thus submits that Claim 31 clearly and nonobviously defines over the cited references. Additionally, Applicant submits that Claims 34-48 and 124 also define over the cited references, not only because they depend from Claim 31, but also on their own merit.

The Proposed Combination of Marogil/Smith Does Not Make Amended Claims 99-102 and 125 Obvious

Claims 99-102 and 125 stand rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Design Patent No. 386,684 issued to Marogil (“Marogil”) in view of Smith. Applicant respectfully traverses the present rejection. However, to expedite the prosecution of the present Application, Applicant has amended Claim 99. Applicant submits that no new matter has been

added and that the amendments are supported in the specification. Applicant reserves the right to further prosecute the original version of Claim 49 through continuation practice.

Marogil teaches an ornamental design for an antiseptic spray nozzle and guard. See Figure 1 of Marogil reproduced below. Smith is discussed above.



On page 6 of the Office Action, the Examiner notes that “it would have been obvious... to provide the splash shield of Marogil with the flexible sheet taught by Smith.”

Applicant disputes that the Smith shield is a *sheet*. Rather, the Smith shield is a *conical* splash shield that appears to be nearly identical in shape as the conical splash shield of Marogil. Thus, Applicant submits that **one of ordinary skill in the art would not combine one conical splash shield over another conical splash shield**. Applicant submits that there is no logical reason why one of ordinary skill in the art would *duplicate two essentially identical components*, i.e., the conical splash shield of Marogil and the conical splash shield of Smith.

Even if one of ordinary skill in the art would do that, no obvious combination of the Smith Marogil conical splash shields would result in an irrigation comprising a flat transparent flexible sheet having an **elastically enlargeable aperture that is configured to fit over and releasably engage a head of an irrigation device which has a narrowed collar and a larger distal rim** so that the elastically enlargeable aperture remains connected to the irrigation device.

In contrast, Claim 99 now recites, among other recitations, “a flat transparent flexible sheet having an elastically enlargeable aperture configured to fit over and releasably engage a head of an irrigation device comprising a flexible splash shield having proximal collar and a conical body that diverges in a distal direction away from the collar toward a distal rim,[[;]] wherein the

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elastically enlargeable aperture when in a relaxed state is smaller than the distal rim end and thereby remains connected to the irrigation device, wherein the flexible sheet is sized to cover a wound area and an irrigation basin”.

Similarly to the comments noted above with regard to the patentability of Claim 31, Applicant also notes that Greco also fails to teach or suggest such an **elastically enlargeable aperture which would fit over any of the conical splash shields of either Smith or Marogil**.

Thus, Applicant submits that Claim 99 clearly and nonobviously defines over the cited references. Additionally, Applicant submits that Claims 100-102 and 125 also define over the cited references, not only because they depend from Claim 99, but also on their own merit.

Dependent Claims 32, 34-48, 100-102, 124, and 125 Depend from Independent Claims 31, 49, or 99

Applicant submits that Claims 32, 34-48, 100-102, 124, and 125 and also define over the cited references, not only because they depend from one of Claims 31, 49, or 99, but also based on of their own unique features.

#### No Disclaimers or Disavowals

Although the present communication may include alterations to the Application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this Application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present Application.



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**SUMMARY**

The undersigned has made a good faith effort to respond to all of the rejections and objections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully requested to call Applicant's attorney in order to resolve such issue promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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